K072407

Theken Spine, LLC BodyForm™ Thoracic Fixation System

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

Submitter's Name:	Theken Spine, LLC
Address:	283 E. Waterloo Akron, Ohio 44319
Telephone Number:	330-773-7677 x221
Fax Number:	330-773-7697
Contact Person:	Dale Davison
Date Prepared:	8/21/07

DEC 2 1 2007

B. Device Information

Trade Name:	BodyForm™ Thoracic Fixation System
Common Name:	Anterior Spinal Fixation System
Classification:	**KWQ** 888.3060 – Spinal Intervertebral Body Fixation Orthosis
Predicate Device:	BodyForm™ Thoraco-Lumbar Fixation System, Theken Spine, LLC (K983622) Thoracolumbar Spine Locking Plate System, Synthes (K020244) Coral Spinal System, Theken Spine, LLC (K041592)
Device Description:	The purpose of this submission is for additional sizes of plates and screws for the BodyForm™ Fixation System. This submission includes smaller sized plates and screws intended for the thoracic region of the spine. All implant components are manufactured from medical grade titanium alloy Ti 6Al-4V (ELI) per ASTM F-136.
Intended Use:	The BodyForm™ Thoracic Fixation System is intended as an adjunct to fusion for treatment of thoracic spinal instability as a result of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, spinal stenosis, deformities or curvatures (scoliosis, kyphosis, and/or lordosis), tumor, and anterior fusion following failed previous fusion operations, including pseudoarthrosis. The BodyForm™ Thoracic Fixation System is intended for unilateral use to attach to the anterolateral aspect of the vertebral bodies at levels of fixation from T1 to L1.
Material Composition:	Implant grade titanium alloy Ti 6Al-4V (ELI) per ASTM F-136 and ISO 5832-3.

C. Substantial Equivalence

Theken Spine, LLC believes sufficient evidence exists to reasonably conclude that the BodyForm™ Thoracic Fixation System is substantially equivalent to other legally marketed predicate devices. This is based on the design concept, the use of established known materials, feature comparisons, mechanical testing, indications for use, and engineering analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2007

Theken Spine, LLC
% Mr. Dale Davison
283 E. Waterloo
Akron, OH 44319

Re: K072407
Trade/Device Name: BodyForm™ Thoracic Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 17, 2007
Received: December 17, 2007

Dear Mr. Davison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072407

Theken Spine, LLC BodyForm™ Thoracic Fixation System

Indications for Use

510(k) Number (if known):

The BodyForm™ Thoracic Fixation System is intended as an adjunct to fusion for treatment of thoracic spinal instability as a result of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, spinal stenosis, deformities or curvatures (scoliosis, kyphosis, and/or lordosis), tumor, and anterior fusion following failed previous fusion operations, including pseudoarthrosis.

The BodyForm™ Thoracic Fixation System is intended for unilateral use to attach to the anterolateral aspect of the vertebral bodies at levels of fixation from T1 to L1.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brechner

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K072407